



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

HL

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/140,886	08/26/98	WILSON	H N1205-003

ROTHWELL FIGG ERNST & KURZ
SUITE 701-E
555 13TH STREET NW
WASHINGTON DC 20004

HM12/0607

EXAMINER

ZAGHMOUT, O

ART UNIT	PAPER NUMBER
1649	4

DATE MAILED: 06/07/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/140,886

Applicant(s)

Wilson et al.

Examiner

Ousama Zaghmout

Group Art Unit

1649



☒ Responsive to communication(s) filed on 8-26-1998, 10-6-1998, 5-4-1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-22 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-22 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2 and 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1649

DETAILED OFFICE ACTION

Claims 1-22 are pending.

A copy of the signed IDS (1449 form) is enclosed.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Ist Paragraph

Claims 1, 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method of obtaining a transgenic plant having an improved agronomic characteristic by transforming plant cells of a recipient plant species with

Art Unit: 1649

DNA fragments from DNA of a donor plant species. However, Applicants have not disclosed a transgenic plant that is transformed by the claimed methods. In the DNA fragments of a donor plant species, there are a number of regulatory elements such as promoters, enhancers, positive and negative trans-acting factors, and introns. If said elements are to be present downstream of the promoter of the vector expression vector, the likelihood of obtaining a transgenic plant with agronomic traits does not exist. Moreover, the chances that a gene with a desirable traits to be present directly downstream of the promoter of the expression vector used in the transformation does not exist either. If it happens that the promoter is directly upstream of the coding gene with a desirable trait, the likely of obtaining a transgenic plant with desirable trait again does not exist due to the presence of a leaky terminator. Accordingly, one of skill in the art would not have recognized the Applicants to have been in possession of transgenic plants obtained by the claimed methods. Therefore, these claims are rejected under 35 U.S.C. 112, first paragraph for failing to comply with the description of the invention requirement.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a method of obtaining a transgenic plant having an improved agronomic characteristic by transforming plant cells of a recipient plant species with

Art Unit: 1649

DNA fragments from DNA of a donor plant species. However, Applicants have not disclosed a transgenic plant that is transformed by the claimed methods. In the DNA fragments of a donor plant species, there are a number of regulatory elements such as promoters, enhancers, positive and negative trans-acting factors, and introns. If said elements are to be present downstream of the promoter of the vector expression vector, the likelihood of obtaining a transgenic plant with agronomic traits does not exist. Moreover, the chances that a gene with a desirable traits to be present directly downstream of the promoter of the expression vector used in the transformation does not exist either. If it happens that the promoter is directly upstream of the coding gene with a desirable trait, the likely of obtaining a transgenic plant with desirable trait again does not exist due to the presence of a leaky terminator.

Furthermore, the distance between the promoter in the plant expression vector used in the transformation and the transcribed unit which encodes a protein with a desirable traits might be at a point where the transcriptional activity of the promoter will not be as effective in transcribing a gene which might fall under its direction. Again, under such conditions, no transgenic plants with improved agronomic characteristics will be produced. Applicants failed to address many of these important issues which are essential for the enablement of this invention.

Moreover, the reduction to practice of a transgenic plant that express genes with improved agronomic characteristics is essential to determine that the claimed method is enabled as a method of improving the agronomic characteristics of a transgenic plant. This is because

Art Unit: 1649

the expression of a transgene does not depend only on the integration into the host genome, said transgene has to be activated which is then has to go through a number of steps such as the initiation of transcription, transcript process, transport to cytoplasm and translation of mRNA. Applicants have failed to address many of these important issues which are essential for the enablement of the invention as claimed in the instant application. The specification is silent as to the criteria used to identify transgenic plants that express the improved agronomic traits. Applicants have provided no specific guidance as to how to select the nucleotide sequences which will produce a protein or a polypeptide conferring the desired effect. One wishing to practice the invention is left to proceed through trial-and-error to see what will work and what will not. Hence, due to the lack of any working examples of the inventions, and the inability of one skilled in the art to predict which if any of all possible proteins which will be useful in the manner suggested, and the unpredictability of the field, it would require undue experimentation to practice the claims .

In view of the breadth of the claims, unpredictability, lack of guidance in the specification of the results as stated above, it is the examiner's position that one skilled in the art to which it pertains, or with which it is most nearly connected, could not practice the invention commensurate in scope with these claims without undue experimentations.

Claim Rejections - 35 USC § 102

Art Unit: 1649

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 8-9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Masoud et al [Plant Molecular Biology. 1993. Vol. 21: 655-663].

The claims are directed to a method for obtaining a transgenic plant comprising the claimed method steps as well as a transgenic plant produced by the claimed method.

Masoud et al teach a method for the production of transgenic tobacco plant having an improved agronomic characteristic which method comprises the expression of the nucleotide sequence which encodes a cysteine proteinase inhibitor isolated from a DNA of rice, a donor plant species (lines 1-3, page 655). Masoud et al teach that the gene which encodes cysteine proteinase inhibitor was cloned into a vector prior to transforming plant cells (Materials and Methods). Masoud et al teach the selection of transformed plant cells, the collection of the seeds from the regenerated plants in order to be used in the screening process. Masoud et al further teach the planting of the harvested seeds (second paragraph of second column, page

Art Unit: 1649

656), the analyzing and the selection of plants which express a cysteine proteinase inhibitor, an improved agronomic characteristics (see Results). In view of the breadth of the claims, each element of the claims is disclosed by the reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Art Unit: 1649

Claims 1-22 are rejected under 35 U.S.C. § 103 as being unpatentable over Masoud et al [Plant Molecular Biology. 1993. Vol. 21: 655-663] in view of Hamilton et al [Proc Natl Acad Sci U S A. 1996 Sep 3;93(18):9975-9979].

The claims are directed to a method for obtaining a transgenic plant comprising the claimed method steps as well as a transgenic plant produced by the claimed method.

Masoud et al teach a method for the production of transgenic tobacco plant having an improved agronomic characteristic which method comprises the expression of the nucleotide sequence which encodes a cysteine proteinase inhibitor isolated from a DNA of rice, a donor plant species (lines 1-3, page 655). Masoud et al teach that the gene which encodes cysteine proteinase inhibitor was cloned into a vector prior to transforming plant cells (Materials and Methods). Masoud et al teach the selection of transformed plant cells, the collection of the seeds from the regenerated plants in order to be used in the screening process. Masoud et al further teach the planting of the harvested seeds (second paragraph of second column, page 656), the analyzing and the selection of plants which express a cysteine proteinase inhibitor, an improved agronomic characteristics (see Results).

Masoud et al does not specifically teach a method for the production of transgenic plants that are transformed by more than one DNA fragment. However this is cured by the teaching of Hamilton et al.

Art Unit: 1649

Hamilton et al teach a method for making a new binary bacterial artificial chromosome (BIBAC) vector that is capable of transferring at least 150 kb of foreign DNA into a plant nuclear genome. Hamilton et al teach that the transferred DNA appears to be intact in the majority of transformed tobacco plants analyzed and is faithfully inherited in the progeny. Hamilton et al teach that the ability to introduce high molecular weight DNA into plant chromosomes should accelerate gene identification and genetic engineering of plants and may lead to new approaches in studies of genome organization (lines 1-10, page 9975).

Given the recognition of those of ordinary skill in the art of the value of producing transgenic plants having improved agronomic characteristics as taught by Masoud et al and where said transgenic plants can be used in gene identification and genetic engineering of plants as taught by Hamilton et al, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the process of Masoud et al and to modify it by incorporating (BIBAC) vector as taught by Hamilton et al which allows the cloning and expression of a number of genes at the same time, in order to produce the methods and the transgenic plants as claimed in the instant application. Furthermore, the use of breeding methods in selecting transgenic plants with an improved agronomic traits is a very common practice during the incorporation of newly produced transgenic plants into the ongoing breeding programs. The use of a DNA from a donor plant such as sorghum and transforming it into a recipient plant such as corn or the cloning of a DNA fragment between two selectable

Art Unit: 1649

markers is a matter of choice unless the proof of criticality is provided. Thus the claimed invention would have been prima facie obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Art Unit: 1649

Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Ousama M-Faiz Zaghmout whose telephone number is (703) 308-9438. The Examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, L. Smith, can be reached on (703) 308-3909. The fax phone number for the group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to THE MATRIX CUSTOMER SERVICE CENTER whose telephone number is (703) 308-0196.

Ousama M-Faiz Zaghmout Ph.D.

June 3, 1999


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600